

218 NEW RD
EAST AMHERST, NY 14051
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DOCKETS MANAGEMENT BRANCH (HFA-305)
FOOD AND DRUG ADMINISTRATION
5630 FISHERS LANE ROOM 1061
ROCKVILLE, MD 20857-0003

RE: DOCKET NO. 98N-1265

To the FDA:

I send this letter as a consumer of health care services to register my concern and disapproval of the Memorandum of Understanding as published by the FDA on January 21, 1999.

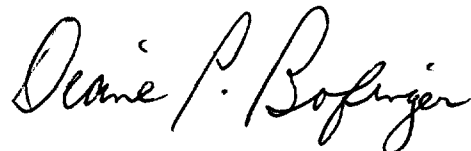
I am a woman who uses compounded hormones from the Women's International Pharmacy in Madison, Wisconsin. I can not tolerate oral hormones and need to use 3-4 Estraderm patches to achieve effective levels of ERT. The patches work well, but are often inconvenient, especially in the summer when they don't stay on well. I am absolutely relieved to have this type of ERT and HRT available, to have a physician who will prescribe them, and to be able to get these products from out-of-state. Because of a hysterectomy/oophorectomy at age 41, I will be using these products for a long time and absolutely need them to be a productive citizen.

In its present form, the MOU, as well as the Compounding Section 503A of the Modernization Act, severely restricts the rights of the physicians and patients to obtain healthcare products from the provider of their choice. It also infringes on the rights of compounding pharmacists to serve the public's medical needs. As a healthcare consumer there should be no restrictions to the delivery of compounded medication prescribed for me, regardless of where I live or travel. The MOU must be amended!!!

The FDA is an agency of the U.S. Government that purports to be the "watchdog" for consumer safety. THIS IS NOT A SAFETY ISSUE!! As a governmental agency, the FDA also has a responsibility to be accountable to the people. Once again, the MOU must be amended!!

Thank you for your consideration of this important matter.

Sincerely,

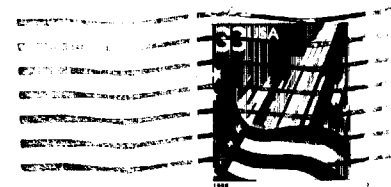


Diane P. Bofinger

98N-1265

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